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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,274	12/27/2001	C. Michael Philbrook	5052	8081

24536 7590 03/03/2005

GENZYME CORPORATION
LEGAL DEPARTMENT
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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/033,274

Applicant(s)

PHILBROOK ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
4a) Of the above claim(s) 1-17 and 27-32 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 18-26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, petition for extension of time, information disclosure statement, request for continued examination, and power of attorney form, all received on 21 December 2004.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 18-26 under 35 U.S.C. 103(a) over Sawhney *et al.* (hereinafter Sawhney I) in view of Levy *et al.* is hereby withdrawn.

Claims 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Sawhney I, Sawhney (hereinafter Sawhney II), and Levy *et al.*

The Sawhney I patent teaches a highly adherent drug delivery system which is biodegradable, biocompatible, and can be adapted for various surgical and therapeutic applications (See Abstract). In one embodiment, a tissue surface may be primed with a photoinitiator and a polymer solution applied onto the same location. When system polymerizes upon exposure to light, the resulting gel exhibits a high adherence at the interface (See Column 3, Lines 1-16). Various monomers may be used in the disclosed invention, including an acrylate-capped polyethylene glycol macromer (See Column 7, Lines 1-19). The polymer system may be

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applied to various tissue surfaces including the pericardium (See Column 12, Lines 15-34).

Various active agents may be incorporated (See Column 12, Line 35 to Column 14, Line 17).

Additional hydrophilic polymers may be incorporated into the biodegradable macromers, including polyvinylpyrrolidone and dextran (See Column 9, Lines 17-26). Material properties, such as viscosity, may be adjusted and tailored to suit the particular application of the polymer system (See Column 17, Lines 24-38). The system may be packaged in a convenient manner, such as in a kit, the materials are contained in three vials or syringes, wherein the initiator and the monomers are kept separate until it is ready to be applied (See Column 17, Lines 39-67).

Sawhney I does not disclose the use of anti-arrhythmic agents, not does it make specific mention of the form of the active agent as it is incorporated into the polymer system.

The Sawhney II patent teaches pharmaceutically acceptable hydrogel polymers which may deliver therapeutic agents *in situ* (See Abstract). Suitable hydrogels include polyethylene oxide (See Column 6, Lines 41-63), as well as those hydrogels based on covalent networks formed by the polymerization of acrylic terminated, water-soluble polymers (See Column 8, Lines 55-65). One particular example of such a polymer is a polyethylene glycol diacrylate macromonomer, used as a 10% solution (See Example 1). Suitable active agents that may be incorporated into the hydrogels include anti-arrhythmic agents. Suitable agents may be soluble in the polymer solution for form a homogeneous mixture, or they may be insoluble in the polymer solution to suspension or dispersion (See Column 13, Line 61 to Column 14, Line 25).

The Levy *et al.* patent discloses site-specific delivery systems of anti-arrhythmic agents comprising a polymeric matrix and an incorporated therapeutic agent for direct placement at the

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epicardium (See Abstract). Amiodarone is listed among the suitable active agents for use in the disclosed invention (See Column 6, Lines 19-66).

It would be obvious for one of ordinary skill in the art to combine the teachings of the aforementioned references into the objects of the instantly claimed invention. One of ordinary skill in the art, knowing the benefits of the transmural administration of amiodarone, would be motivated to incorporate this same active agent into the polymer systems as taught by the Sawhney references, as the polymer systems taught in those references can be safely and effectively be administered *in situ* to deliver active agents in a biodegradable vehicle. As the references all deal with polymeric systems of the *in situ* delivery of active agents, they are considered to be analogous art. Thus, one of ordinary skill in the art would have a reasonable expectation of success in combining the references together.

Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments with respect to Claims 18-26 have been considered but are moot in view of the new grounds of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1615

sj0

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

